(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 June 2015 (18.06.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/089083 A1

(51) International Patent Classification:
A61B 17/74 (2006.01)

(21) International Application Number:
PCT/US2014/069363

(22) International Filing Date:
9 December 2014 (09.12.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/913,593 9 December 2013 (09.12.2013) US

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(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,

[Continued on next page]

(54) Title: PLATE-BASED COMPLIANT HIP FIXATION SYSTEM

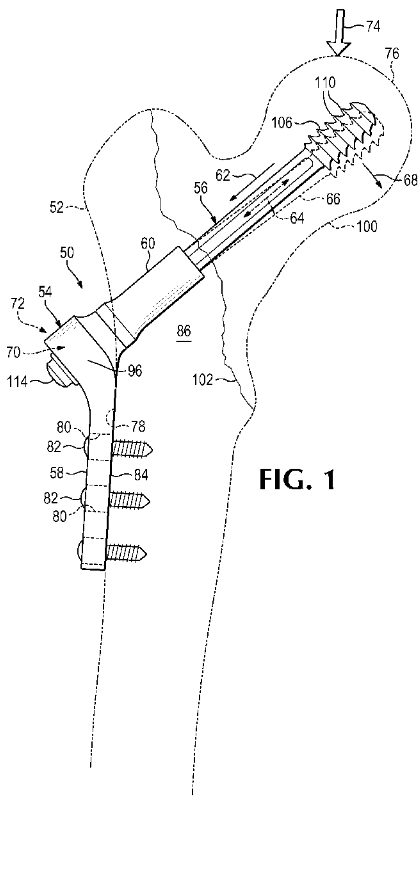

FIG. 1

(57) Abstract: System, including methods, devices, and kits, for hip fixation. The system may include a fixation element configured to be placed obliquely into a proximal femur and anchored in a head of the proximal femur. The system also may include a plate member including (a) a mounting portion configured to be placed on and attached to a lateral cortex of the proximal femur and (b) a barrel portion configured to be placed into a lateral region of the proximal femur and positioned around a portion of the fixation element. The system further may include a compliant member positioned or positionable at least partially in the plate member and configured to be reversibly deformed in response to a load applied to the head of the proximal femur, to change an angular orientation of the fixation element with respect to the plate member.

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DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

PLATE-BASED COMPLIANT HIP FIXATION SYSTEM

Cross-Reference to Priority Application

This application is based upon and claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application Serial No. 61/913,593, filed December 9, 2013, which is incorporated herein by reference in its entirety for all purposes.

Introduction

The hip joint is a synovial joint formed by articulation of the head of the femur with the acetabulum of the pelvis. The hip joint(s) supports the weight of the body when a person is standing, walking, or running, among others.

Trauma to the femur can fracture the femur near the hip joint. Depending on the position and severity of fracture, the femoral head may be replaced with a prosthesis, or the bone may be stabilized with an implanted fixation device to hold the femoral head in position while the femur heals.

A plate-based fixation device involving a side plate and a sliding screw is commonly utilized for fixation. The side plate has a barrel portion for receiving a portion of the screw. The screw is inserted obliquely into the proximal femur from a lateral side thereof, such that the screw extends through the femoral neck and into the femoral head, and generally bridges at least one fracture. The screw may, for example, be placed at an angle about 135 degrees with respect to the femur, to account for the angle between the femoral head/neck and the femoral shaft. The side plate then is affixed to the lateral side of the proximal femur, with the barrel extending into the proximal femur and surrounding a trailing portion of the screw.

The screw may not be fixed with respect to the barrel of the side plate. Instead, the screw may be permitted to slide parallel to its long axis in the barrel. Accordingly, the screw can migrate laterally (anatomically) after installation, for dynamic compression of the fracture, which can encourage and improve fracture healing.

The ability of the screw to slide along its axis can improve performance dramatically. Nevertheless, the fixation device does not always provide a successful outcome. In some cases, the femoral head is damaged by cut-out, where migration of the femoral head relative to the screw causes the screw to project through the articular surface of the femoral head, and/or to split the femoral head.

An improved plate-based fixation system is needed.

Summary

The present disclosure provides a system, including methods, devices, and kits, for hip fixation. The system may include a fixation element configured to be placed obliquely into a proximal femur and anchored in a head of the proximal femur. The system also may include a plate member including (a) a mounting portion configured to be placed on and attached to a lateral cortex of the proximal femur and (b) a barrel portion configured to be placed into a lateral region of the proximal femur and positioned around a portion of the fixation element. The system further may include a compliant member positioned or positionable at least partially in the plate member and configured to be reversibly deformed in response to a load applied to the head of the proximal femur, to change an angular orientation of the fixation element with respect to the plate member.

Brief Description of the Drawings

Figure 1 is a front view of an exemplary compliant hip fixation system installed in a fractured proximal femur and including a side plate (a plate member) and a slideable fixation element projecting out of a barrel portion of the side plate, with angular motion of the fixation element shown in phantom outline, in accordance with aspects of the present disclosure.

Figure 2 is an exploded isometric view of the hip fixation system of Figure 1 taken in the absence of the proximal femur.

Figure 3 is a sectional view of the fixation system of Figure 1 taken through a central plane of the system.

Figure 4 is a fragmentary sectional view of the hip fixation system of Figure 1, sectioned as in Figure 3 and taken around a lateral portion of the system with the fixation element not loaded.

Figure 5 is a fragmentary sectional view of the hip fixation system of Figure 1, taken as in Figure 4 after loading the fixation element such that its angular orientation changes as a compliant interface of the system deforms.

Figure 6 is a fragmentary, partially sectional view of another exemplary compliant hip fixation system, constructed similarly to the hip fixation system of Figure 1 except that the barrel portion is only one piece, in accordance with aspects of the present disclosure.

Figure 7 is a sectional view of the hip fixation system of Figure 6, taken generally along line 7–7 of Figure 6 through a bearing element of the system.

Figure 8 is a fragmentary, partially sectional view of yet another exemplary compliant hip fixation system, taken through a central plane of the system and containing a perforated compliant member, in accordance with aspects of the present disclosure.

Figure 9 is a fragmentary, partially sectional view of still another exemplary compliant hip fixation system, taken through a central plane of the system and containing a perforated compliant member as in Figure 8 except with a longer sleeve, in accordance with aspects of the present disclosure.

Figure 10 is a fragmentary sectional view of the fixation systems of Figures 8 and 9, taken generally along line 10–10 of Figures 8 and 9 through the perforated compliant member of each system.

Figure 11 is a fragmentary sectional view of yet still another exemplary compliant hip fixation system, taken generally as in Figure 3 through a central plane of the system, with the system utilizing the perforated compliant member of Figure 8 and lacking a discrete bearing element between the fixation element and the barrel portion near the leading end of the barrel portion.

Figure 12 is a fragmentary sectional view of still yet another exemplary compliant hip fixation system, taken generally as in Figure 11 through a central plane of the system, with the system utilizing a sleeve and a compliant member each disposed in the barrel portion and extending along a majority of the length of the barrel portion.

Figure 13 is a fragmentary sectional view of another exemplary compliant hip fixation system, taken generally as in Figure 11 through a central plane of the system, with the system structured similarly to that of Figure 12 except with the compliant member formed by a pair of deformable elements that are spaced from one another along the sleeve, in accordance with aspects of the present disclosure.

Figure 14 is a fragmentary sectional view of yet another exemplary compliant hip fixation system, taken generally as in Figure 3 through a central plane of the system and having a compliant member arranged obliquely to a slideable fixation element, in accordance with aspects of the present disclosure.

Figure 15 is a fragmentary sectional view of the hip fixation system of Figure 14 with a different washer, in accordance with aspects of the present disclosure.

Detailed Description

The present disclosure provides a system, including methods, devices, and kits, for hip fixation. The system may include a fixation element configured to be placed obliquely into a proximal femur and anchored in a head of the proximal femur. The system also may include a plate member including (a) a mounting portion configured to be placed on and attached to a lateral cortex of the proximal femur and (b) a barrel portion configured to be placed into a lateral region of the proximal femur and positioned around a portion of the fixation element. The system further may include a compliant member positioned or positionable at least partially in the plate member and configured to be reversibly deformed in response to a load applied to the head of the proximal femur, to change an angular orientation of the fixation element with respect to the plate member.

The hip fixation system of the present disclosure may have a reduced stiffness (greater compliance), to reduce the peak loads created at the implant-bone interface (in the femoral head), thereby reducing the propensity for micro-crack formation, which can ultimately lead to cut-out of the implant through the femoral head. Accordingly, the hip fixation system may have various advantages over existing hip fixation systems including a lower incidence of cut-out through the femoral head, improved patient comfort, better force dampening, less swarf created through wear, and/or the like.

Further aspects of the present disclosure are described in the following sections: (I) overview of plate-based compliant hip fixation systems, (II) methods of bone fixation, (III) composition of system components, (IV) kits, and (V) examples.

I. Overview of Plate-based Compliant Hip Fixation Systems

This section describes exemplary plate-based hip fixation systems having a slideable fixation element, such as a screw, extending out of a barrel portion of a plate member and angularly oriented with respect to the plate member by a compliant interface.

Figures 1-5 show various views of an exemplary hip fixation system 50 installed in a fractured proximal femur 52 (Figure 1) or in the absence of the femur (Figures 2-5). System 50 (interchangeably termed an implant or a device) may include a plate member 54 (interchangeably termed a side plate) intersected by, connected to, and/or assembled with, a fixation element 56 (which may be termed a fastener, and in some cases, a hip screw and/or a lag screw). Plate member 54 may include a mounting portion 58 and a barrel portion 60. Plate member 54 interchangeably may be termed a support member including a plate portion (mounting portion 58) and barrel portion 60.

Fixation element 56 may be slideable, indicated by a motion arrow at 62, relative to proximal femur 52, plate member 54, and/or barrel portion 60 on an axis 64 (see Figure 1). Axis 64 may be coaxial to the central long axis of fixation element 56 and may be movable, as described in more detail below, to change an angular orientation of the fixation element with respect to proximal femur 52 and/or plate member 54 (and/or mounting portion 58 and/or barrel portion 60), indicated in phantom outline at 66 and by a motion arrow at 68. Fixation element 56 may retain the ability to slide along its long axis as its angular orientation varies. In some embodiments, the fixation element may not be slideable in barrel portion 60 after the fixation system is fully installed in the femur. In some embodiments, fixation element 56 may be slideable in both directions parallel to the long axis of the fixation element. In some embodiments, the fixation element may be slideable laterally and not substantially medially along the long axis of the fixation element.

Plate member 54 may at least partially contain a compliant member 70 (see Figures 1-5), which may be discrete from plate member 54 and/or fixation element 56. The compliant member alternately may be described as a biasing member or a deformable member. Compliant member 70 forms at least part of a compliant interface 72 (which may be described as a deformable and/or biasing interface) that permits angular motion of fixation element 56, shown at 66 and 68 in Figure 1. For example, a downward force or load 74 applied to the inner end of fixation element 56 via bone, such as when a subject (the implant recipient) is standing or walking, applies a torque to fixation element 56. The torque may cause deformation of compliant member 70 and an accompanying change in the angular orientation of the entire fixation element. Deformation of the compliant member may absorb some of the load applied to the hip joint and may help to govern and cushion load transfer during use of the hip joint (such as when walking). Fixation element 56 may change its angular orientation in a varus direction, indicated at 68, in response to load 74 (see Figure 1). The attached femoral head 76 can move with the fixation element, producing varus travel of the femoral head, which may reduce the tendency of the fixation element to move relative to the femoral head.

Changes to the angular orientation of the fixation element may be dynamic as the subject moves. For example, these changes may be cyclical when the subject walks. The fixation element may move toward a more perpendicular (and/or more varus) orientation with respect to the femoral long axis when load 74 is applied (i.e., when the associated femur is bearing the weight of the subject) and may move back to a more oblique (and/or more valgus) orientation when load 74 is removed (e.g., when the contralateral femur is bearing the weight of the subject).

Compliant interface 72 may permit fixation element 56 to change its angular orientation with respect to plate member 54, mounting portion 58, and/or barrel portion 60 by any suitable amount from a relatively neutral or unloaded (“home”) configuration during normal use, such as less than about 5 or 2 degrees, or at least about 0.2, 0.5, or 1 degree, among others. The end of the fixation element in the femoral head and farthest from the plate member may have a maximum range of motion from the neutral or unloaded configuration during normal use of less than about 5 mm or 2 mm, or greater than about 0.5 mm or 1 mm, among others.

The compliant member (and/or compliant interface) is resilient (interchangeably termed elastic), meaning that the compliant member (and/or compliant interface) is capable of substantially recovering its previous shape and size after being deformed (i.e., after a deforming force/load is removed). The resiliency of the compliant member (and/or compliant interface) may store energy and then use the stored energy to urge the fixation element back toward a neutral/unloaded position or orientation when the load is reduced or removed. The compliant member may be viscoelastic. In some embodiments, the compliant member may be described as a spring. The compliant member can act as a mechanical damper, which may absorb energy to function as a cushion, particularly to absorb sudden impacts produced by standing up, walking, running, etc.

In some embodiments, the compliant member may provide non-linear load resistance/absorption. For example, as the compliant member is deformed, further deformation may be progressively more difficult and the load needed for further deformation may increase non-linearly. The compliant member may be formed of a single material or may be a composite of two or more materials, such as metal and polymer, to provide optimal dampening.

Mounting portion 58 may be configured to be positioned at least predominantly or exclusively outside the femur. The mounting portion may be placed on and attached to a lateral cortex 78 of the femur, with a long axis of the mounting portion extending longitudinally along the femur (see Figure 1). The mounting portion may define at least one or a plurality of apertures 80 for receiving fasteners, such as bone screws 82, that secure the mounting portion to the proximal femur. Each aperture 80 may be arranged outward of only one side of fixation element 56 and/or barrel portion 60, as shown, such that each aperture is positioned inferiorly along the femur with respect to the barrel portion after the system has been fully installed. Alternatively, apertures 80 may bracket the long axis of the fixation element and/or barrel portion, such that one or more apertures 80 are superior along the femur with respect to a junction where the barrel portion meets the mounting portion after the system has been fully installed. Each aperture 80 may or may not have an internal thread for attaching a fastener, such as a bone screw 82, to the mounting portion. Each fastener placed into bone from an aperture 80 may, for example, engage the femur unicortically, as shown in Figure 1, or bicortically, among others.

The mounting portion may have a lower profile on bone than shown in Figure 1. For example, the mounting portion may have a thickness (T) that is substantially less than its length (L) and width (W), where L>W (e.g., L is at least twice W) and W is at least about twice or four times T. Also, mounting portion 58 may have a bone-facing surface 84 (also called an inner side or inner surface) that is concave transversely, generally parallel to a width dimension of the mounting portion.

Barrel portion 60 may be configured to be positioned at least partially or at least predominantly or substantially exclusively inside the femur. Barrel portion 60 may be configured to extend into a lateral region 86 of the femur (see Figure 1). The barrel portion may be formed integrally with (or separately from) mounting portion 58. Accordingly, the barrel portion may or may not be removable from the mounting portion and may or may not have a fixed orientation with respect to the mounting portion. The barrel portion may be flexibly or rigidly (e.g., integrally) connected to the mounting portion. The barrel portion may project from the mounting portion, such as from bone-facing surface 84, at an obtuse angle, such as at an angle of greater than about 110 degrees or about 120-150, 125-145, or 130-140 degrees, among others. The barrel portion may be rigid or flexible. In some embodiments, the barrel portion defines one or more slots or other openings that render the barrel portion flexible, to allow the fixation element to change its angular orientation.

The barrel portion may have any suitable external shape. The outside diameter of the barrel portion may be constant or may vary along the barrel portion. For example, the barrel portion may be round in cross section and the external shape may be cylindrical, conical, spherical, or a combination thereof, among others.

Plate member 54 may define a channel 88 for receiving and surrounding a portion of fixation element 56 (see Figures 2 and 3). The channel may extend through plate member 54, and particularly through barrel portion 60 on an axis 90. The channel has an outer end 92 and an inner end 94 (see Figure 3). Outer end 92 may be described as being defined by a junction region 96 of plate member 54, which may be formed by mounting portion 58 and/or barrel portion 60.

Channel 88 may have any suitable shape. The channel may or may not vary in diameter. If the diameter varies, this variation may be a taper or stepwise, or both, among others. In some embodiments, the channel may widen at outer end 92, which may form a countersink 98, and/or may narrow (or widen) at inner end 94 (see Figure 3). In some embodiments, the channel may widen and then narrow at one or more positions intermediate the opposite ends of the channel. In some embodiments, the channel may be conical, cylindrical, or spherical, among others, optionally along a majority of the channel length. For example, channel 88 tapers toward inner end 94 to give the channel a conical shape (see Figure 3).

Compliant member 70 may be positioned or positionable at least partially in channel 88. For example, the compliant member may be located in countersink 98 (see Figures 2 and 3) and/or elsewhere along channel 88, such as in barrel portion 60 at one position or two or more spaced positions along the channel (see Section V).

Fixation element 56 may be configured to be disposed partially in channel 88, such that the fixation element extends along a majority of the length of the channel and out inner end 94 of channel 88, through femoral neck 100 and into femoral head 76, for anchorage in the femoral head (see Figure 1). The fixation element may bridge one or more femoral fractures 102. (The plate member, such as the mounting portion and/or the barrel portion, also may bridge one or more of the same or different fractures.)

Fixation element 56 may have a shaft 104, and a bone-securing portion 106 extending from the leading end of the shaft (see Figure 2). Shaft 104 may be configured to slide parallel to the shaft’s long axis inside channel 88 at various angular orientations of the shaft produced by deformation of compliant interface 72. The shaft may be a single piece, or two or more pieces, which may be assembled inside or outside the femur. The shaft may be at least generally cylindrical. The shaft may be shaped to prevent the fixation element from turning about the fixation element's long axis after the barrel portion has been placed around the shaft. For example, the shaft may have one or more flats 108, grooves, and/or ridges, among others, extending along the shaft that engage a corresponding or complementary region formed by a wall of channel 88 or an element disposed therein (see below).

Bone-securing portion 106 may (or may not) be wider than shaft 104 of fixation element 56. In any event, bone-securing portion 106 forms one or more anchoring features to anchor the fixation element in the femoral head. In the depicted embodiment, bone-securing portion 106 defines an external thread 110 that attaches the bone-securing portion to femoral head 76 (see Figures 1 and 2). Accordingly, the fixation element may be a screw. In other embodiments, bone-securing portion 106 may define one or more blades, flanges, spikes, deployable talons, etc., or any combination thereof, among others, to provide anchorage in the femoral head. The bone-securing portion may not (or may) be advanceable through channel 88, which may (or may not) require that the fixation element be installed in the proximal femur before a portion of shaft 104 of the fixation element is received in channel 88.

Fixation element 56 may have any other suitable structure. The fixation element may be configured to apply compression to the femur, such as across at least one fracture 102 spanned by fixation element 56 (see Figure 1). The fixation element may define an internal thread 112 for attachment to a compression screw 114, and/or may define an axial bore 116 extending through the fixation element (see Figure 4). The fixation element also may define an internal and/or external driver-engagement structure 118 for engagement by a driver that turns or otherwise urges the fixation element into bone (see Figure 2). The driver-engagement structure may, for example, be at least one slot, a socket (e.g., a hexagonal socket), external flats (e.g., a hexagonal, faceted perimeter), etc.

Figures 2-4 show further aspects of barrel portion 60 and a bearing element 120 captured therein. Barrel portion 60 may include an inner tube 122 and an outer tube 124 or collar circumferentially surrounding the inner tube. Inner tube 122 may be formed integrally with mounting portion 58 and may define a substantial longitudinal portion (and/or all) of channel 88. Outer tube 124 may be secured to inner tube 122 with an end portion of the outer tube projecting beyond the end of the inner tube. Bearing element 120 may be trapped in a space 126 near the inner end of channel 88 (see Figure 4).

Bearing element 120 facilitates angular motion of fixation element 56 in one or more planes containing the long axis of the fixation element, to change the angular orientation (e.g., the tilt) of the long axis of fixation element 56 with respect to plate member 54. Bearing element 120 defines an opening 128 and a through-axis 130 along which fixation element 56 extends through opening 128. The wall of opening 128 may be in contact with the fixation element and may have a low coefficient of friction with the exterior of the fixation element’s shaft, such that the fixation element can slide readily in opening 128 parallel to through-axis 130. The bearing element may be sized and shaped to pivot, rock, or otherwise change its angular orientation in one or more planes containing through-axis 130, to change the angular orientation of through-axis 130 with respect to the central long axis of channel 88 (compare Figures 4 and 5). For example, the bearing element may have a periphery 132 with convex curvature in a plane containing through-axis 130. In other words, the bearing element may have opposite ends that are spaced from one another in a direction parallel to through-axis 130, and the outside diameter of the bearing element may increase toward a central region of the bearing element that is intermediate both opposite ends of the bearing element. At least a portion of the periphery of bearing element 120 may be at least generally spherical. Space 126 may be bounded circumferentially by a cylindrical wall. In other examples, bearing element 120 may restrict rotation of fixation element 56 about the long axis of the fixation element after installation of the fixation system has been completed and/or may restrict angular motion of the long axis of the fixation element substantially to one plane of a set of three mutually orthogonal planes (see Example 1 of Section V). In some embodiments, angular motion of the fixation element may be substantially restricted to a frontal plane, such that anterior/posterior motion of the fixation element is less than motion in the frontal plane. However, the system may be designed to permit any suitable amount of anterior/posterior motion of the fixation element.

The fixation element may change its angular orientation about a pivot axis or center of rotation, which may be fixed or movable with respect to the fixation element and/or barrel portion as the angular orientation changes. The pivot axis or center of rotation may be inside or outside the barrel portion.

Figures 2-5 show further aspects of how compliant member 70 may be held in channel 88 and positioned with respect to fixation element 56. Compliant member 70 may be received in countersink 98 such that the compliant member cannot rotate about the central long axis of channel 88. For example, the compliant member may have one or more flats 134 that engage corresponding flats defined by the wall of countersink 98 (see Figure 2).

Compliant member 70 may be separated from fixation element 56 by a bushing 136 (also called a sleeve) received in an opening 138 of the compliant member (see Figures 2 and 4). The bushing may contact the shaft of fixation element 56 and may have a low coefficient of friction with the shaft to permit axial motion of the fixation element with respect to the bushing. Opening 138 may be configured to prevent rotation of the fixation element about its long axis. For example, the wall of opening 138 may form flats that contact flats 108 formed on the shaft of the fixation element (see Figure 2). The outside of bushing 136 may be configured to be attached to compliant member 70 such that the bushing and the compliant member (as a unit) cannot move relative to one another. For example, the bushing may define barbs 140 or other retention structure that engages an inside surface of compliant member 70 (see Figure 4). Accordingly, rotation of the fixation element about its long axis may be restricted by contact with bearing element 120 and/or bushing 136, among others.

A retainer 142 may engage the outer face of compliant member 70 to prevent removal of the compliant member from channel 88 (see Figures 2 and 4). The retainer may have an external thread 144 that attached to an internal thread 146 formed in channel 88. The retainer may define holes 148 or other driver-engagement structure to permit the retainer to be driven into attachment with plate member 54. A head of compression screw 114 may bear against retainer 142, during installation, as the compression screw is tightened, to apply compression to the proximal femur via fixation element 56. Dynamic compression of the femur that occurs after installation of the fixation system may permit the fixation element to slide in a lateral direction with respect to the femur, which may move the head of compression screw 114 out of contact with retainer 142. The retainer may define an opening 150 that is oversized with respect to a shaft 152 of compression screw 114, to permit shaft 152 to move in a direction across the opening as the tilt of the fixation element changes (compare Figures 4 and 5).

Compliant member 70 may have any suitable location and structure. The compliant member may be at least partially contained by plate member 54 and thus may be disposed at least partially or completely inside barrel portion 60 and channel 88. Based on the position along the fixation element where angular motion is centered, the compliant member may be disposed at least partially superior to (above) the fixation element, at least partially or predominantly inferior to (below) the fixation element, or both, among others. Accordingly, the compliant member may bracket a shaft portion of the fixation element and/or may surround the shaft portion.

The compliant member, or at least a portion thereof, may be discrete from or continuous with the plate member. The compliant member may include only a single deformable element or two or more discrete deformable elements, such as upper and lower deformable elements or axially spaced deformable elements that collectively form the compliant member (e.g., see Example 4 of Section V).

Compliant member 70 may provide radially uniform or radially nonuniform resistance to angular motion (and/or permit radially uniform or radially nonuniform ranges of angular motion) of fixation element 56 with respect to plate member 54. The compliant member may not completely surround any portion of fixation element 56, as shown, or may extend completely around the fixation element at one or more positions along the fixation element. Also, the thickness of the compliant member may (or may not) vary around and/or along the fixation element. Accordingly, the compliant member may provide differential resistance to angular motion of the fixation element in opposite rotational directions in a plane, or may offer an equal resistance in both rotational directions in the plane.

In the depicted embodiment, fixation element 56 has a greater range of angular motion in a frontal plane defined collectively by plate member 54 and fixation element 56 collectively, relative to a plane that is orthogonal to the frontal plane and contains the long axis of fixation element 56. Also, resistance to angular motion, and/or the range of angular motion, of fixation element 56 in the frontal plane may be different in opposite rotational directions (clockwise (varus for the fixation element) and counterclockwise (valgus for the fixation element) in Figure 4), from the neutral or unloaded (home) position of the fixation element. The resistance to moving the fixation element to a more orthogonal orientation with respect to the femur (clockwise in Figure 4) may be less than the resistance to moving the fixation element to a less orthogonal orientation with respect to the nail (counterclockwise in Figure 4), from an unloaded orientation, or vice versa.

Compliant member 70 and/or each deformable element thereof may have any suitable properties. The compliant member may, for example, be formed of a polymer, and may be described as an elastomeric member. The compliant member may be formed in situ (e.g., in channel 88 of plate member 54 or may be formed separately from the plate member and then placed into the channel 88 after formation (e.g., during manufacture or during a surgical procedure to install the fixation system). The radial wall thickness of the compliant member may be uniform or may vary.

Further aspects of fixation systems for the femur or any other suitable bone are described elsewhere herein, such as in Section V, and in U.S. Provisional Patent Application Serial No. 61/913,593, filed December 9, 2013, which is incorporated herein by reference.

II. <u>Methods of Bone Fixation</u>

This section describes exemplary methods of bone fixation using any of the devices disclosed herein. The method steps described in this section may be performed in any suitable order and combination and may be combined with any other steps or device features disclosed elsewhere herein.

A bone to be fixed may be selected. The bone may be a femur or a humerus, among others. The bone may have at least one discontinuity, such as at least one fracture. The discontinuity may be disposed in a proximal end region of the bone. For example, the discontinuity may be disposed generally between the shaft and the head of the bone. In some embodiments, the bone may be a fractured proximal femur having at least one fracture intersecting the neck, intertrochanteric, and/or pertrochanteric region(s) of the femur. Accordingly, the fracture(s) may intersect the femoral neck, the greater trochanter, the lesser trochanter, the shaft, or a combination thereof.

The bone may be prepared for receiving at least a portion of a fixation implant. For example, one or more holes may be drilled in the bone to receive at least part of a fixation element, a barrel portion of a plate member, and fasteners. Also, pieces of the bone may be moved relative to another to reduce the fracture(s).

One or more incisions through skin and other overlying soft tissue may be created to access the bone.

The bone-securing portion of the fixation element may be placed into the head of the bone. For example, the bone-securing portion may be driven into the head by application of torque (i.e., by turning the bone-securing portion), percussive force (e.g., striking a portion of the fixation element), or a combination thereof, among others. The bone-securing portion and the shaft of the fixation element may be placed into the bone as a unit, or at least part of the shaft may be placed into the bone after the bone-securing portion has been installed in bone.

A plate member may be selected for attachment to the bone and assembly with the fixation element. The plate member may be selected based on the size of the fixation element, the size and condition of the bone (e.g., the position and number of fractures or other discontinuities), and/or the like.

A compliant member (and/or one or more deformable elements thereof) may be selected to form a compliant interface between the plate member and the sliding fixation element. The compliant member may be pre-assembled with the plate member (i.e., during manufacture), such that selection of the plate member also selects the compliant member. Alternatively, the compliant member may be assembled with the plate member/fixation element after manufacture, such as in the operating room by a surgeon or supporting personnel.

The compliant member may be selected peri-operatively based on one or more characteristics of the subject (i.e., the implant recipient and/or patient), such as according to the subject's weight, age, health, fitness level, activity level, or a combination thereof, among others. Selection of a patient-specific compliant member may modulate load dampening in a patient-appropriate manner and/or may optimize the amount of micromotion at the fracture site(s) needed by the patient for efficient healing. The compliant member, if a removable/interchangeable component(s), may be assembled with the plate member (e.g., the barrel portion) and/or the fixation element at any suitable time.

The barrel portion of the selected plate member may be placed around at least a portion of the shaft of the fixation element. The barrel portion and the shaft may be arranged at least generally coaxial to one another, with the shaft extending out of an inner end of the barrel portion. The barrel portion may be placed into bone before or after the fixation element is inserted into bone.

The mounting portion of the selected plate member may be attached to bone with one or more fasteners, such as bone screws. The mounting portion may be arranged longitudinally on the bone, such as extending along the shaft portion of the bone.

The fixation element may be adjusted to urge the head of the bone at least generally toward the bone's shaft. For example, a compression screw may be attached to the shaft of the fixation element and tightened against the plate member or an element disposed therein and/or thereon.

The incision(s) may be closed over the implant. The implant may be left in place permanently or may be removed after the bone has healed.

III. <u>Composition of System Components</u>

This section describes exemplary materials for construction of components of the hip fixation system.

The plate member, the fixation element (and/or other fasteners), and the compliant member may be formed of any suitable biocompatible material(s). Exemplary biocompatible materials that may be suitable for the plate member, sliding fixation element, and/or compliant member include (1) metal (for example, titanium or titanium alloys, alloys with cobalt and chromium (cobalt-chrome), stainless steel, etc.); (2) plastic/polymer (for example, ultra-high molecular weight polyethylene (UHMWPE), thermoplastic polyurethane (TPU), polymethylmethacrylate (PMMA), polytetrafluoroethylene (PTFE), polyetheretherketone (PEEK), nylon, polypropylene, and/or PMMA/polyhydroxyethylmethacrylate (PHEMA)); (3) composites (e.g., a polymer matrix (such as PEEK) containing carbon fibers and/or ceramic); (4) bioresorbable (bioabsorbable) materials or polymers (for example, polymers of α-hydroxy carboxylic acids (e.g., polylactic acid (such as PLLA, PDLLA, and/or PDLA), polyglycolic acid, lactide/glycolide copolymers, etc.), polydioxanones, polycaprolactones, polytrimethylene carbonate, polyethylene oxide, poly-β-hydroxybutyrate, poly-β-hydroxypropionate, poly-δ-valerolactone, other bioresorbable polyesters, etc.; and/or the like.

In exemplary embodiments, the plate member is formed of metal; all or part of the fixation element is formed of metal; and the compliant member is formed of metal (e.g., spring steel), polymer (e.g., an elastomer (such as thermoplastic polyurethane)), or a combination thereof. In some embodiments, the compliant member (and/or at least one deformable element thereof) may, for example, include a metal portion (e.g., a core or base) and a polymer portion (e.g., a coating disposed on the metal portion). The polymer portion may be attached to the metal portion during formation (such as by overmolding the polymer portion onto the metal portion) or after formation (such as with an adhesive, bonding, etc.).

IV. Kits

The hip fixation system may be provided as a system or kit with two or more different options for at least one of the components. For example, the system/kit may include two or more plate members of different size and/or shape, two or more fixation elements of different size (e.g., different lengths and/or different diameters), and/or two or more interchangeable compliant members of different deformability (e.g., different flexibility/stiffness, range of motion, relative deformability in a pair of orthogonal planes, etc.).

V. Examples

The following examples describe selected aspects and embodiments of the present disclosure including exemplary hip fixation systems and methods of installing the systems to fix a proximal femur. The components, aspects, and features of the systems described in each of these examples may be combined with one another and with the devices described above, in any suitable combination. These examples are intended for illustration and should not limit the entire scope of the present disclosure.

Example 1. Hip Fixation System with Swaged Barrel Portion

This example describes an exemplary hip fixation system 160 with a one-piece barrel portion 60 having a swaged end 162 that captures a bearing element 120 inside the barrel portion; see Figures 6 and 7.

Hip fixation system 160 may be structured generally as described above for system 50 (see Section I). However, barrel portion 60 may be generated initially with a cylindrical flange 164 (shown in phantom outline in Figure 6) that is sized to receive bearing element 120. A lip portion of flange 164 then may be deformed, such as rolled radially inward, to prevent removal of the bearing element from channel 88.

Barrel portion 60 and bearing element 120 may cooperate to prevent rotation of fixation element 56 about its long axis and to restrict angular motion of the fixation element to one plane of a set of three mutually orthogonal planes (see Figure 7). Barrel portion 60 may define one or more inside flats 166 that contact one or more corresponding outside flats 168 of bearing element 120. The bearing element also may define one or more inside flats 170 that contact one or more flats 108 on the shaft of fixation element 56.

Example 2. Hip Fixation System Having a Perforated Compliant Member

This example describes exemplary compliant hip fixation systems 180, 190 having a perforated compliant member 192 or 194 that contacts the fixation element; see Figures 8-10.

Fixation systems 180 and 190 may have any combination of the elements and features described elsewhere herein. For example, each system may have a compression screw and a retainer (see Figures 2 and 4), which are not shown here to simplify the presentation.

Compliant member 192 may define a central opening 196 in which fixation element 56 can slide. The compliant member may have a low coefficient of friction with the fixation element, which allows the compliant member and fixation element to slideably contact one another. For example, compliant member 192 may be formed of metal or smooth, relatively hard plastic. The wall of central opening 196 may define flats 198 that cooperate with flats 108 of fixation element 56.

Compliant member 192 may include an outer, perimeter ring 200, a hub or inner ring 202 defining central opening 196, and a plurality of connecting elements 204 (which interchangeably may be termed struts, spring members, or spokes) extending from outer ring 200 to hub 202. Each connecting element 204 may extend separately between the outer ring and the hub or one or more of the connecting elements may branch intermediate the ring and the hub. In some examples, the connecting elements may be replaced by a meshwork. In any event, the connecting elements may extend nonlinearly (or linearly) from outer ring 200 to hub 202. Each connecting element may extend radially, or at least generally tangentially with respect to hub 202 (as shown in Figure 10). The connecting elements may vary in thickness along each connecting element or among the connecting elements, to tune the deformability of the compliant member along each of a pair of axes orthogonal to one another and to the through-axis of channel 88. Accordingly, the connecting elements may provide a thicker web and a thinner web, respectively, where needed to restrict or permit deformation. The connecting elements may contact and bind on each other as the compliant member deforms, to limit or stop deformation. Compliant member 192 may define a plurality of apertures 206 flanking connecting elements 204.

Compliant member 194 may be similar to compliant member 192 except having an integrally formed sleeve portion 210 that extends axially from hub 202 (compare Figures 8 and 9; also see Figure 10). The sleeve portion may function to distribute the load exerted on compliant member 194 by fixation element 56, such that the fixation element remains slideable axially in the sleeve portion when the fixation element is loaded, rather than potentially binding on hub 202.

Example 3. Hip Fixation System with a Barrel Portion as a Bearing Element

This example describes an exemplary compliant hip fixation system 220 having a barrel portion 60 with an inside wall region 222 that slideably contacts a fixation element 56; see Figure 11.

Fixation system 220 may be structured generally as described above for hip fixation system 180 (see Figures 8 and 10). However, bearing element 120 may be omitted. Instead, fixation element 56 may movably contact wall region 222 formed integrally with or fixed in relation to barrel portion 60 and, optionally, formed integrally with mounting portion 58. Wall region 222 may (or may not) be shaped to restrict rotation of fixation element 56 about its long axis and/or to restrict angular motion of the fixation element to one plane of a set of three mutually orthogonal planes.

Example 4. Hip Fixation System with an Elongate Sleeve

This example describes exemplary compliant hip fixation systems 240, 250 having a barrel portion 60 containing an elongate sleeve 252; see Figures 12 and 13.

Fixation system 240 may have an inner sleeve 252 resiliently mounted in barrel portion 60 via a compliant member 70 formed as an outer sleeve 254 extending along a majority of the length of inner sleeve 252. The inner sleeve may, for example, be formed of metal or hard plastic, and the outer sleeve may, for example, be formed at least partially of an elastomer.

Fixation system 250 may be structured similarly to system 240 except that compliant member 70 is formed by a pair of deformable rings 256, 258 that are axially spaced from one another, such as arranged around respective opposite ends regions of sleeve 252.

Example 5. Hip Fixation System with Oblique Compliant Member

This example describes an exemplary compliant hip fixation system 270 having a compliant member 70 and a retainer 142 arranged obliquely to a long axis of the fixation element; see Figures 14 and 15.

Hip fixation system may be structured generally as described above for hip fixation system 50, except that the plate member may have a lower profile on the femur, to reduce soft tissue irritation and improve patient comfort. To provide a lower profile, each of compliant member 70, bushing 136, and retainer 142 may be arranged obliquely to a central long axis 90 of channel 88. Retainer 142 may include an underlying member 272 and a washer 274 (Figure 14) or 274A (Figure 15).

Each washer 274 or 274A defines a respective opening 276 through which a compression screw 114 extends. The compression screw may have a head 278 with a spherical underside 280 that engages the wall of the opening. Opening 276 may be at least generally circular (Figure 14) or elongated parallel to the plane to form a slot (Figure 15). The slot also may be elongated in a plane defined collectively by the long axis of the barrel portion (and/or fixation element) and the long axis of the mounting portion of the plate member, and/or in a central plane of the plate member. Accordingly, the slot may be structured to substantially restrict angular travel of the fixation element to a single plane and/or to only one of two opposite rotational directions in a plane.

Example 6. Selected Embodiments I

This example describes selected embodiments of a plate-based hip fixation system having a compliant interface between a plate member and a sliding fixation element, and methods of installing the plate member and fixation element for hip fixation.

Paragraph 1. A system for hip fixation, comprising: (A) a plate member including a mounting portion for attachment to a lateral region of a proximal femur and a barrel portion configured to extend into the lateral portion of the proximal femur; (B) a fixation element for attachment to a head of the proximal femur and configured to be received partially in the barrel portion; and (C) a compliant interface between the plate member and the fixation element and including a biasing member, wherein the fixation element is slideable in the barrel portion along an axis, and wherein the axis is movable (e.g., pivotable) with respect to the mounting portion by reversible deformation of the compliant interface.

Paragraph 2. The system of paragraph 1, wherein the biasing member includes at least one spring.

Paragraph 3. The system of paragraph 2, wherein the at least one spring includes a coil spring, a leaf spring, and/or a torsion spring.

Paragraph 4. The system of any of paragraphs 1 to 3, wherein the biasing member includes is formed at least partially of an elastomer, and wherein the elastomer optionally includes thermoplastic polyurethane.

Paragraph 5. The system of any of paragraphs 1 to 4, wherein the biasing member is viscoelastic.

Paragraph 6. The system of any of paragraphs 1 to 5, wherein the fixation element has a securing portion configured to be disposed in the head of the femur, and wherein the compliant interface is configured such that the securing portion can pivot downward but not upward from a neutral/unloaded position.

Paragraph 7. The system of any of paragraphs 1 to 6, wherein resistance to pivoting the fixation element off-axis from an unloaded configuration is not axisymmetric, and optionally wherein resistance to pivoting the fixation element in a frontal plane in not axisymmetric, and further optionally wherein resistance to varus pivotal motion of the fixation element in the frontal plane is less than resistance to valgus pivotal motion of the fixation element.

Paragraph 8. The system of paragraph 7, wherein the fixation element is pivotable in only one plane.

Paragraph 9. The system of paragraph 7, wherein the fixation element defines a long axis, and wherein the fixation element is configured to be more resistant to pivoting in a frontal plane than in a second plane containing the long axis and orthogonal to the frontal plane.

Paragraph 10. The system of any of paragraphs 1 to 7 and 9, wherein the fixation element defines a long axis, and wherein the fixation element is configured to have a greater range of pivotal motion in a frontal plane than in a second plane containing the long axis and oriented orthogonal to the frontal plane.

Paragraph 11. The system of any of paragraphs 1 to 7, 9, and 10, wherein the mounting portion and the barrel portion collectively define a first plane, and wherein the fixation element is capable of pivotal motion in the first plane and in a second plane containing the long axis and orthogonal to the first plane.

Paragraph 12. The system of any of paragraphs 1 to 11, further comprising a sleeve disposed at least partially in the barrel portion and arranged coaxially with the fixation element.

Paragraph 13. The system of paragraph 12, wherein the biasing member is disposed between the sleeve and the barrel portion.

Paragraph 14. The system of any of paragraphs 1 to 13, wherein the fixation element is movable with respect to the plate member via a pivotable joint that defines a pivot point and/or permits pivotal motion about at least pivot axis transverse to the fixation element, and wherein, optionally, the pivotable joint is formed near an inner end of the barrel portion.

Paragraph 15. The system of paragraph 14, wherein the biasing member is configured to be spaced from the pivot point and/or at least one transverse pivot axis in a direction away from the femoral head.

Paragraph 16. The system of paragraph 14 or 15, wherein the long axis of the fixation element intersects the pivot point and/or the at least one transverse axis.

Paragraph 17. The system of any of paragraphs 1 to 16, wherein the biasing member is arranged coaxially with the long axis of the fixation element.

Paragraph 18. The system of any of paragraphs 1 to 17, wherein the biasing member defines a plurality of apertures.

Paragraph 19. The system of paragraph 18, wherein the biasing member includes an inner ring, an outer ring, and a plurality of struts connecting the inner and outer rings.

Paragraph 20. The system of paragraph 19, wherein the fixation element is configured to extend through the inner ring.

Paragraph 21. The system of any of paragraphs 1 to 20, wherein the barrel portion defines a channel, and wherein a size and/or shape of the channel is variable in response to deforming force applied by the fixation element.

Paragraph 22. A system for hip fixation, comprising: (A) a plate member including a mounting portion for attachment to a lateral region of a proximal femur and a barrel portion configured to extend into the lateral region of the proximal femur from the mounting portion; and (b) a fixation element for attachment to a head of the proximal femur and configured to be received partially in the barrel portion such that the fixation element is slideable with respect to the plate member on an axis extending through the barrel portion, the axis being movable by reversible deformation of a biasing interface operatively intermediate the fixation element and the mounting portion.

Paragraph 23. The system of paragraph 22, wherein the mounting portion and the barrel portion are provided by discrete components.

Paragraph 24. A method of hip fixation, the method comprising: (A) disposing a fixation element in a proximal femur and attached to a head of the proximal femur; (B) disposing a portion of the fixation element in a barrel portion of a plate member; (C) attaching a mounting portion of the plate member to a lateral region of the proximal femur, wherein the fixation element is slideable along an axis and pivotable transverse to the axis by deformation of a biasing interface operatively intermediate the fixation element and the mounting portion.

Paragraph 25. The method of paragraph 24, further comprising a step of selecting a biasing member of the biasing interface based on one or more characteristics of a patient to receive the plate member and fixation element.

Paragraph 26. The method of paragraph 25, wherein the one or more characteristics include a weight and/or size (e.g., height) of the patient.

Paragraph 27. The method of paragraph 25, further comprising a step of assembling the biasing member with the plate member after the step of selecting.

Example 7. Selected Embodiments II

This example describes additional selected embodiments of a plate-based hip fixation system having a compliant interface between a plate member and a sliding fixation element, and methods of installing the plate member and fixation element for hip fixation.

Paragraph 1. A system for hip fixation, comprising: (A) a fixation element configured to be placed transversely into a proximal femur such that the fixation element is anchored in a head of the proximal femur and extends from the head to a lateral region of the proximal femur; (B) a plate member including (i) a mounting portion configured to be placed on and attached to a lateral cortex of the proximal femur and (ii) a barrel portion projecting from the mounting portion and having a channel extending therethrough and configured to be placed into the lateral region of the proximal femur and around a portion of the fixation element such that the fixation element is slideable longitudinally in the channel; and (C) a compliant member positioned or positionable at least partially in the channel and configured to be reversibly deformed in response to a load applied to the head of the proximal femur, to change an angular orientation of the fixation element with respect to the plate member.

Paragraph 2. The system of paragraph 1, wherein the compliant member includes an elastomer.

Paragraph 3. The system of paragraph or paragraph 2, wherein the compliant member is configured to be oriented obliquely to a long axis defined by the fixation element.

Paragraph 4. The system of any of paragraphs 1 to 3, further comprising a sleeve located at least partially within the channel of the plate member and configured to surround a portion of the fixation element and to permit the fixation element to slide longitudinally with respect to the sleeve, and wherein at least a portion of the compliant member is disposed between the sleeve and a wall of the channel.

Paragraph 5. The system of paragraph 4, wherein the sleeve and the compliant member are formed of different materials relative to one another.

Paragraph 6. The system of paragraph 5, wherein the sleeve is formed of metal and the compliant member includes an elastomer.

Paragraph 7. The system of any of paragraphs 1 to 6, further comprising a bearing element disposed at least partially in the channel and defining an aperture to slideably receive a portion of the fixation element along a through-axis of the aperture, and wherein the bearing element is movable in the channel to change an angular orientation of the through-axis with respect to the channel.

Paragraph 8. The system of paragraph 7, wherein the bearing element has a periphery with convex curvature in a plane containing the through-axis.

Paragraph 9. The system of any of paragraphs 1 to 8, wherein the fixation element includes an external thread configured to anchor the fixation element in the head of the proximal femur.

Paragraph 10. The system of any of paragraphs 1 to 9, wherein the fixation element includes a blade configured to anchor the fixation element in the head of the proximal femur.

Paragraph 11. The system of any of paragraphs 1 to 10, wherein the fixation element is configured to be prevented from turning about its long axis after installation in the proximal femur by contact with the barrel portion and/or an element located at least partially in the channel.

Paragraph 12. The system of any of paragraphs 1 to 11, wherein the compliant member is configured to provide a non-axisymmetric resistance to changing the angular orientation of the fixation element from an unloaded configuration.

Paragraph 13. The system of any of paragraphs 1 to 12, wherein the compliant member forms a sleeve or a ring configured to surround a portion of the fixation member.

Paragraph 14. The system of any of paragraphs 1 to 13, wherein the compliant member defines a plurality of openings that render the compliant member deformable.

Paragraph 15. The system of any of paragraphs 1 to 14, wherein the compliant member includes a pair of deformable elements each disposed at least partially in the channel and spaced from one another along the channel.

Paragraph 16. A system for hip fixation, comprising: (A) a screw configured to be placed transversely into a proximal femur such that the screw is in threaded engagement with a head of the proximal femur and extends from the head to a lateral region of the proximal femur; (B) a plate member including (i) a mounting portion configured to be placed on and attached to a lateral cortex of the proximal femur and (ii) a barrel portion at least partially defining a channel configured to be placed at least partially in the lateral region of the proximal femur and around a portion of the screw such that the screw is slideable longitudinally in the channel; (C) a compliant member positioned or positionable at least partially in the channel and configured to be reversibly deformed in response to a load applied to the head of the proximal femur, to change an angular orientation of the fixation element with respect to the plate member, the compliant member including an elastomer; and (D) a bearing element located in the channel and defining an aperture to slideably receive a portion of the fixation element along a through-axis of the aperture, the bearing element being movable in the channel to change an angular orientation of the through-axis with respect to the channel.

Paragraph 17. A method of hip fixation, the method comprising, in any order: (A) placing a fixation element into a proximal femur of a subject such that the fixation element is anchored in a head of the proximal femur and extends from the head to a lateral region of the proximal femur; (B) placing a barrel portion of a plate member into the lateral region of the proximal femur and around a portion of the fixation element; (C) securing a mounting portion of the plate member onto the lateral region of the proximal femur; wherein the fixation element is slideable longitudinally in the barrel portion, and wherein a compliant member is located at least partially in a channel extending through the barrel portion and is configured to be reversibly deformed in response to a load applied to the head of the proximal femur, to change an angular orientation of the fixation element with respect to the plate member.

Paragraph 18. The method of paragraph 17, further comprising a step of selecting the compliant member based on one or more characteristics of the subject, wherein the compliant member is selected from a set of two or more different compliant members each configured to provide a different resistance to changing the angular orientation of the fixation element.

Paragraph 19. The method of paragraph 18, wherein the one or more characteristics include a weight of the subject.

Paragraph 20. The method of paragraph 18 or paragraph 19, further comprising a step of placing the selected compliant member at least partially into the channel that extends through the barrel portion.

The disclosure set forth above may encompass multiple distinct inventions with independent utility. Although each of these inventions has been disclosed in its preferred form(s), the specific embodiments thereof as disclosed and illustrated herein are not to be considered in a limiting sense, because numerous variations are possible. The subject matter of the inventions includes all novel and nonobvious combinations and subcombinations of the various elements, features, functions, and/or properties disclosed herein. The following claims particularly point out certain combinations and subcombinations regarded as novel and nonobvious. Inventions embodied in other combinations and subcombinations of features, functions, elements, and/or properties may be claimed in applications claiming priority from this or a related application. Such claims, whether directed to a different invention or to the same invention, and whether broader, narrower, equal, or different in scope to the original claims, also are regarded as included within the subject matter of the inventions of the present disclosure. Further, ordinal indicators, such as first, second, or third, for identified elements are used to distinguish between the elements, and do not indicate a particular position or order of such elements, unless otherwise specifically stated.

WE CLAIM:

1. A system for hip fixation, comprising:

a fixation element configured to be placed into a proximal femur such that the fixation element is anchored in a head of the proximal femur and extends from the head to a lateral region of the proximal femur;

a plate member including (a) a mounting portion configured to be placed on and attached to a lateral cortex of the proximal femur and (b) a barrel portion projecting from the mounting portion and having a channel extending therethrough and configured to be placed into the lateral region of the proximal femur and around a portion of the fixation element such that the fixation element is slideable longitudinally in the channel; and

a compliant member positioned or positionable at least partially in the channel and configured to be reversibly deformed in response to a load applied to the head of the proximal femur, to change an angular orientation of the fixation element with respect to the plate member.

2. The system of claim 1, wherein the compliant member includes an elastomer.

3. The system of claim 1, wherein the compliant member is configured to be oriented obliquely to a long axis defined by the fixation element.

4. The system of claim 1, further comprising a sleeve located at least partially within the channel of the plate member and configured to surround a portion of the fixation element and to permit the fixation element to slide longitudinally with respect to the sleeve, and wherein at least a portion of the compliant member is disposed between the sleeve and a wall of the channel.

5. The system of claim 4, wherein the sleeve and the compliant member are formed of different materials relative to one another.

6. The system of claim 5, wherein the sleeve is formed of metal and the compliant member includes an elastomer.

7. The system of claim 1, further comprising a bearing element disposed at least partially in the channel and defining an aperture to slideably receive a portion of the fixation element along a through-axis of the aperture, and wherein the bearing element is movable in the channel to change an angular orientation of the through-axis with respect to the channel.

8. The system of claim 7, wherein the bearing element has a periphery with convex curvature in a plane containing the through-axis.

9. The system of claim 1, wherein the fixation element includes an external thread configured to anchor the fixation element in the head of the proximal femur.

10. The system of claim 1, wherein the fixation element includes a blade configured to anchor the fixation element in the head of the proximal femur.

11. The system of claim 1, wherein the fixation element is configured to be prevented from turning about its long axis after installation in the proximal femur by contact with the barrel portion and/or an element located at least partially in the channel.

12. The system of claim 1, wherein the compliant member is configured to provide a non-axisymmetric resistance to changing the angular orientation of the fixation element from an unloaded configuration.

13. The system of claim 1, wherein the compliant member forms a sleeve or a ring configured to surround a portion of the fixation member.

14. The system of claim 1, wherein the compliant member defines a plurality of openings that render the compliant member deformable.

15. The system of claim 1, wherein the compliant member includes a pair of deformable elements each disposed at least partially in the channel and spaced from one another along the channel.

16. A system for hip fixation, comprising:

a screw configured to be placed transversely into a proximal femur such that the screw is in threaded engagement with a head of the proximal femur and extends from the head to a lateral region of the proximal femur;

a plate member including (a) a mounting portion configured to be placed on and attached to a lateral cortex of the proximal femur and (b) a barrel portion at least partially defining a channel configured to be placed at least partially in the lateral region of the proximal femur and around a portion of the screw such that the screw is slideable longitudinally in the channel;

a compliant member positioned or positionable at least partially in the channel and configured to be reversibly deformed in response to a load applied to the head of the proximal femur, to change an angular orientation of the fixation element with respect to the plate member, the compliant member including an elastomer; and

a bearing element located in the channel and defining an aperture to slideably receive a portion of the fixation element along a through-axis of the aperture, the bearing element being movable in the channel to change an angular orientation of the through-axis with respect to the channel.

17. A method of hip fixation, the method comprising, in any order:

placing a fixation element into a proximal femur of a subject such that the fixation element is anchored in a head of the proximal femur and extends from the head to a lateral region of the proximal femur;

placing a barrel portion of a plate member into the lateral region of the proximal femur and around a portion of the fixation element;

securing a mounting portion of the plate member onto the lateral region of the proximal femur;

wherein the fixation element is slideable longitudinally in the barrel portion, and

wherein a compliant member is located at least partially in a channel extending through the barrel portion and is configured to be reversibly deformed in response to a load applied to the head of the proximal femur, to change an angular orientation of the fixation element with respect to the plate member.

18. The method of claim 17, further comprising a step of selecting the compliant member based on one or more characteristics of the subject, wherein the compliant member is selected from a set of two or more different compliant members each configured to provide a different resistance to changing the angular orientation of the fixation element.

19. The method of claim 18, wherein the one or more characteristics include a weight of the subject.

20. The method of claim 18, further comprising a step of placing the selected compliant member at least partially into the channel that extends through the barrel portion.

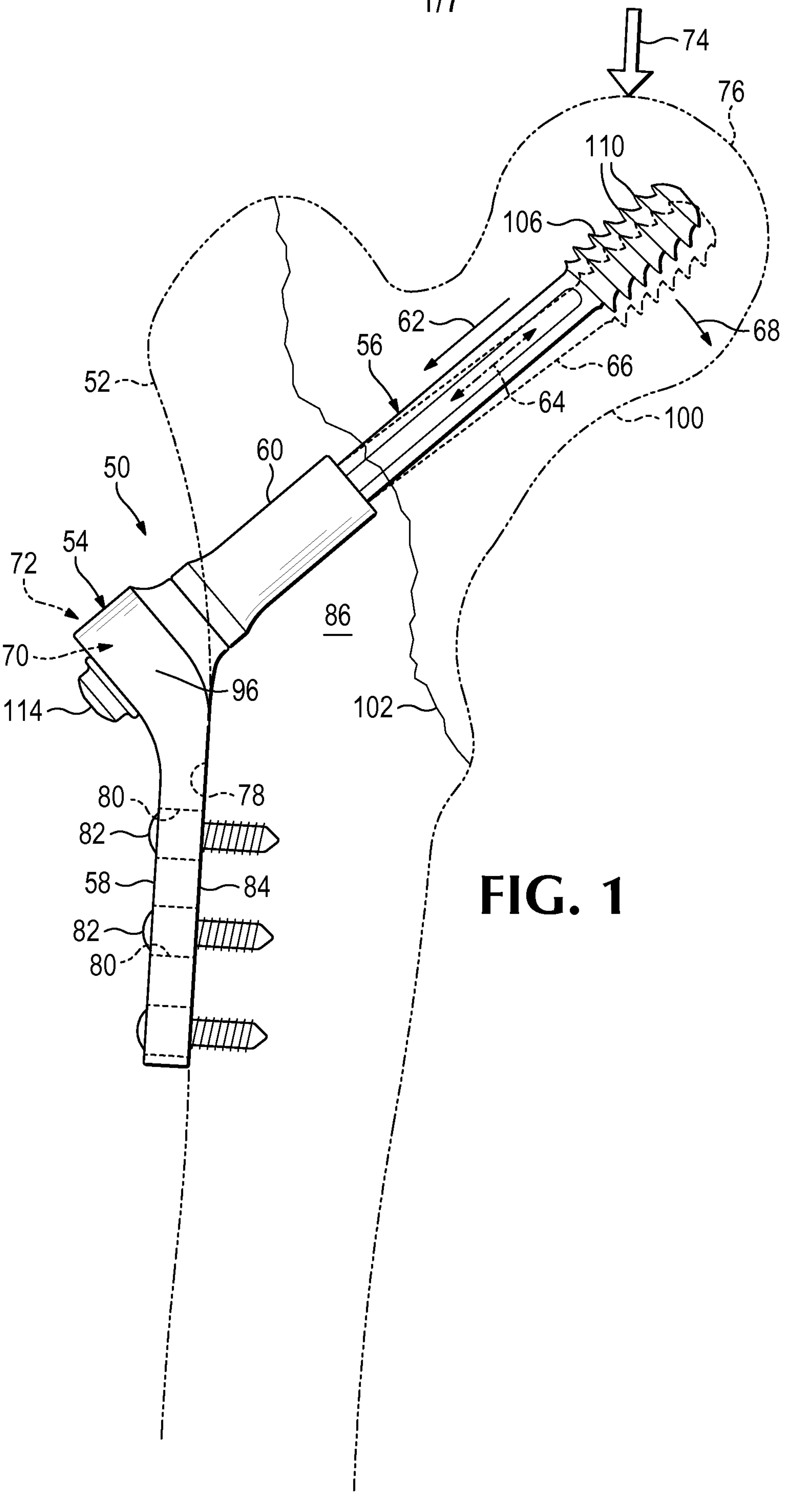
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FIG. 1

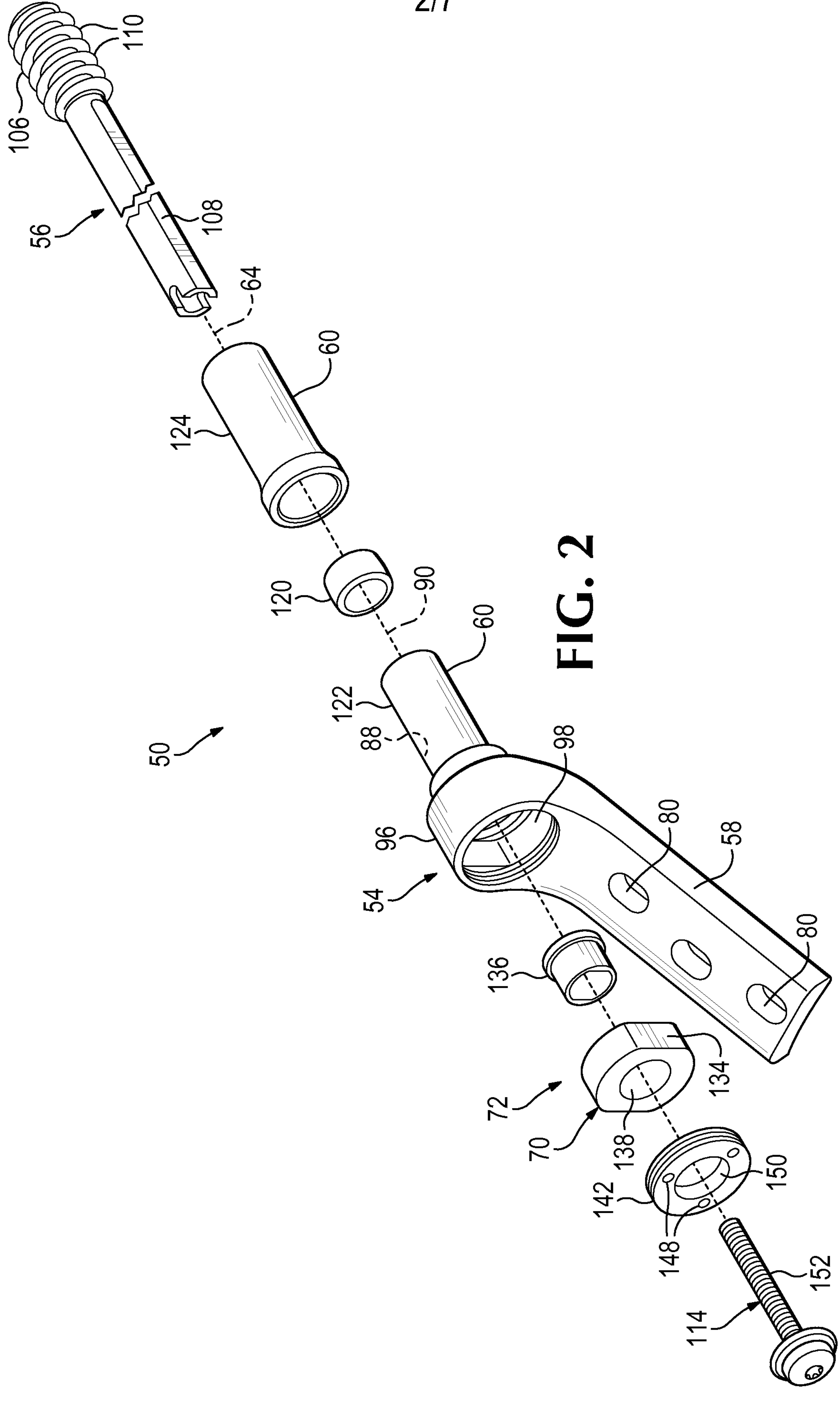
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FIG. 2

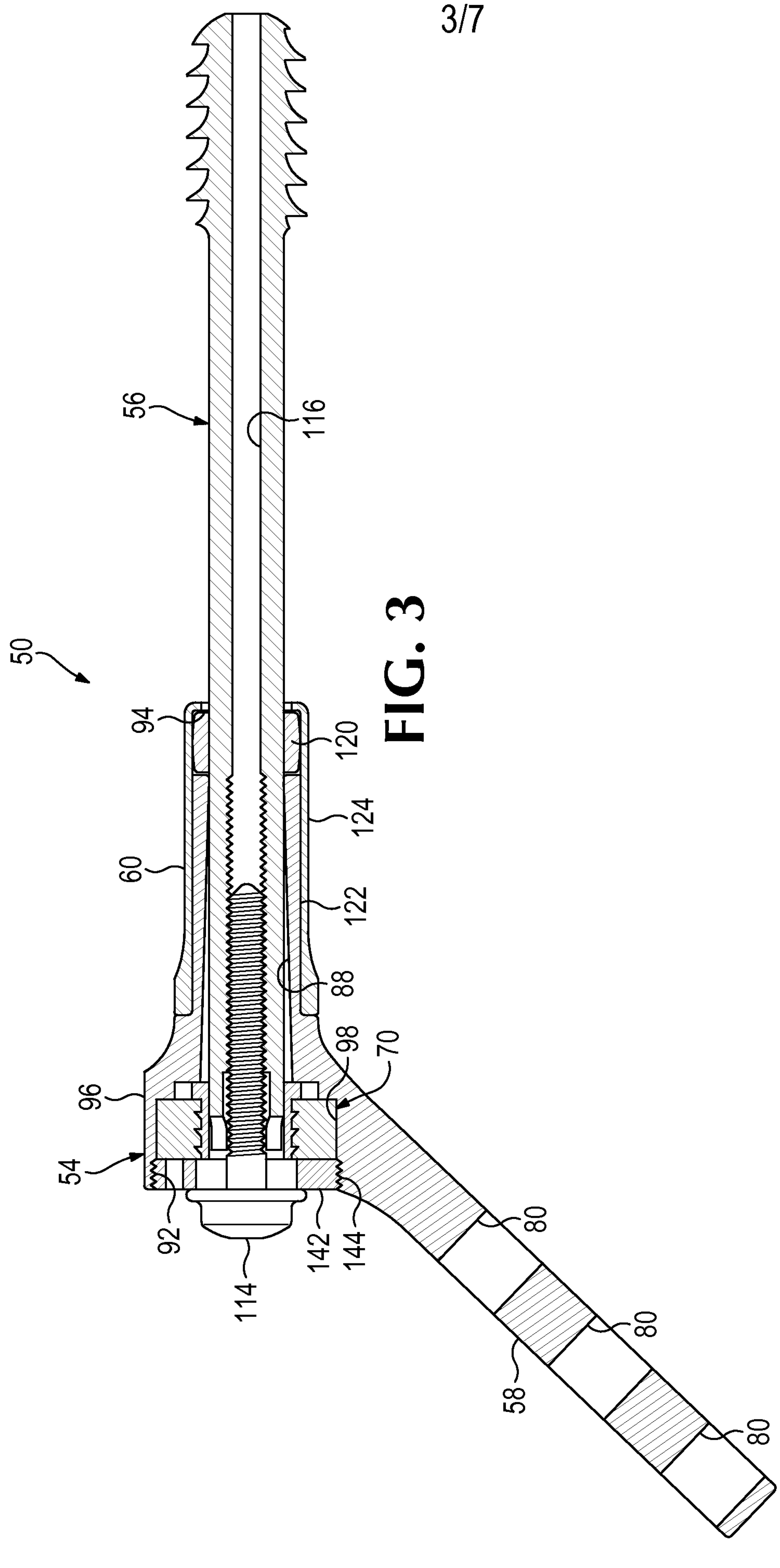


FIG. 3

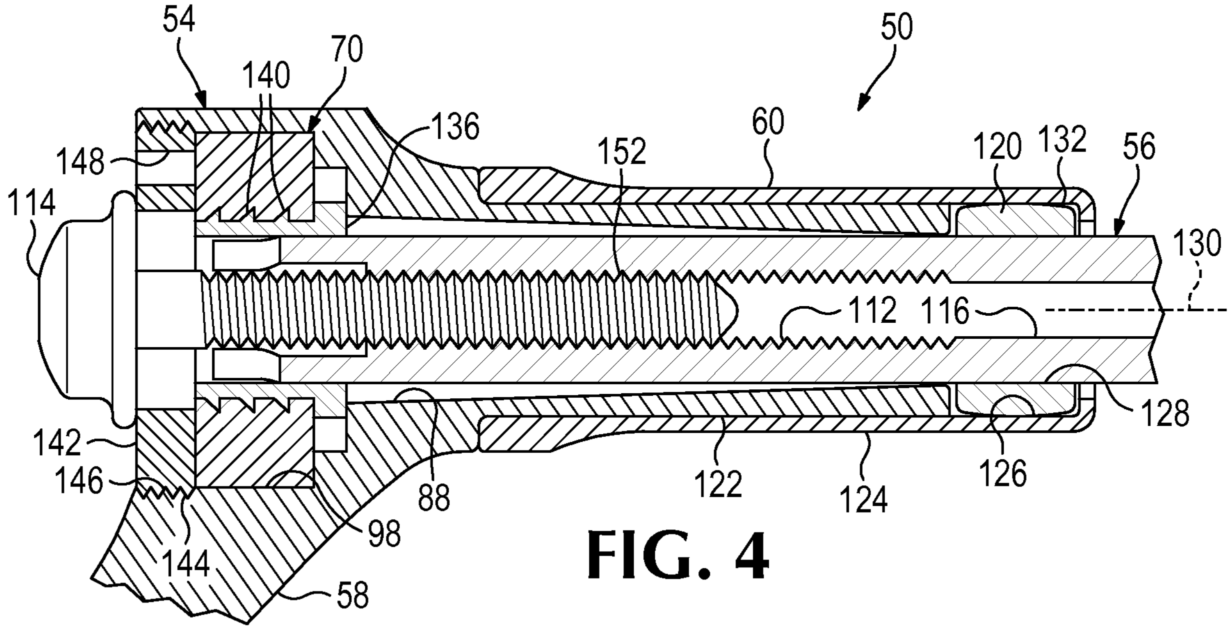


FIG. 4

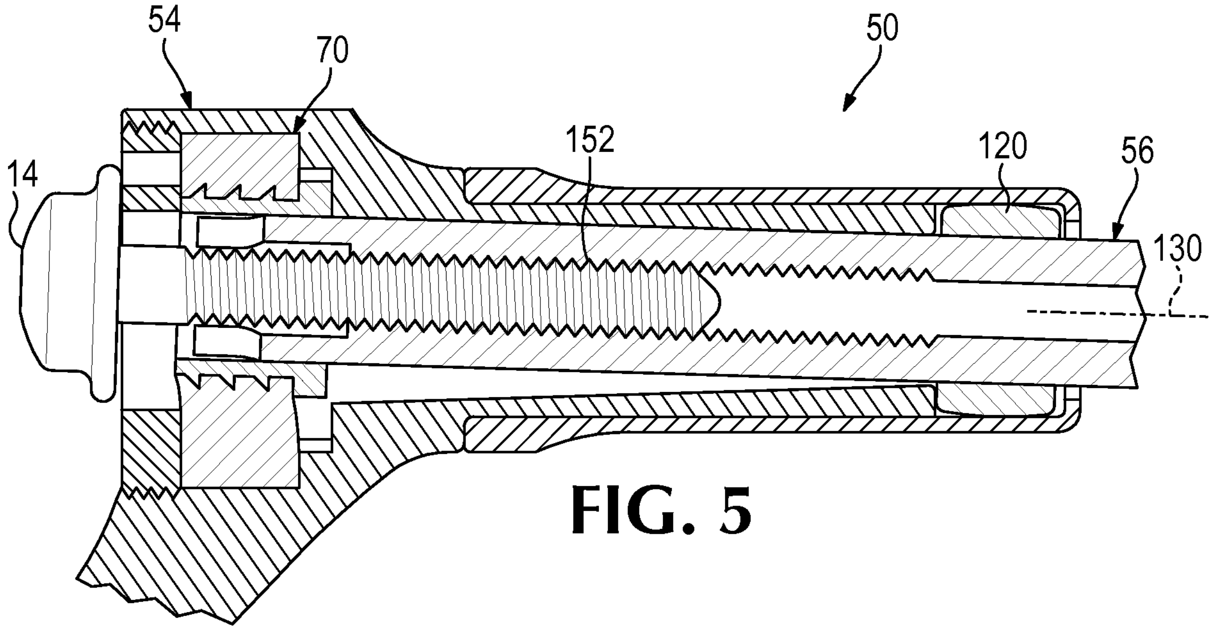


FIG. 5

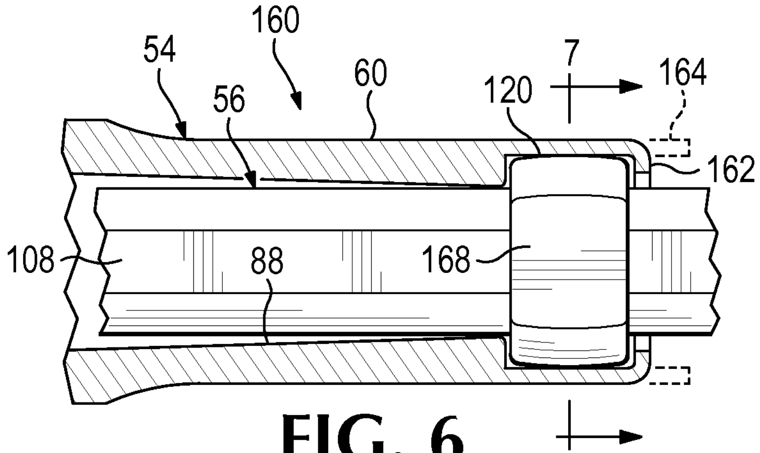


FIG. 6

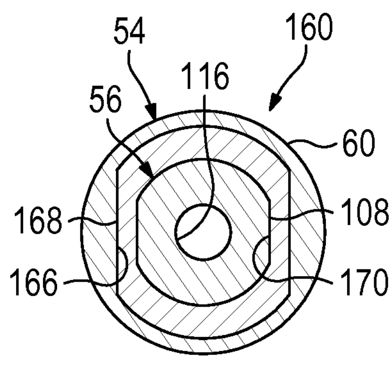


FIG. 7

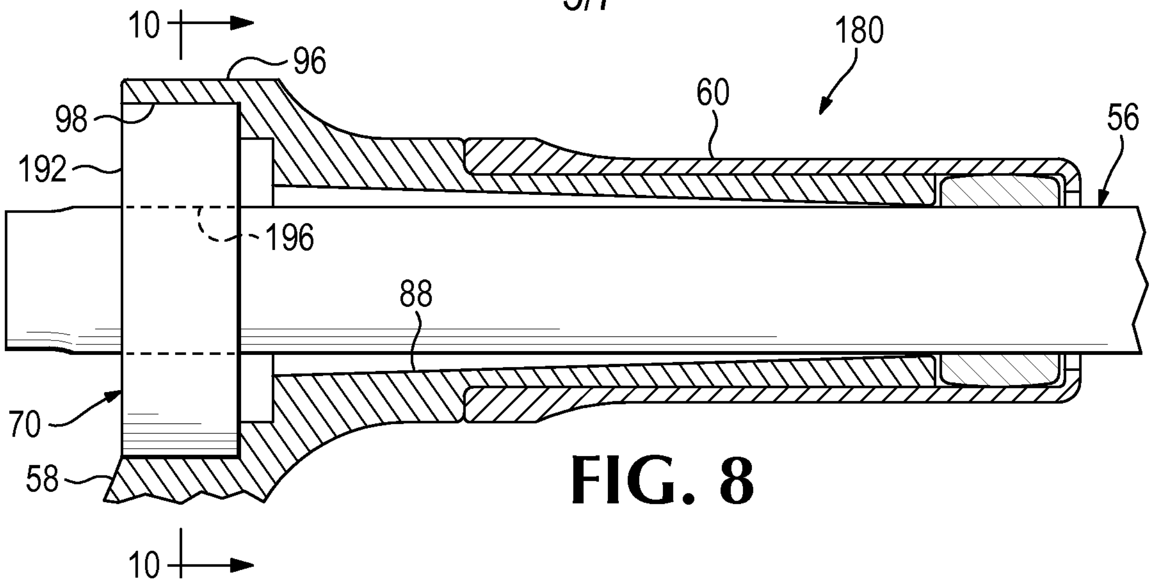


FIG. 8

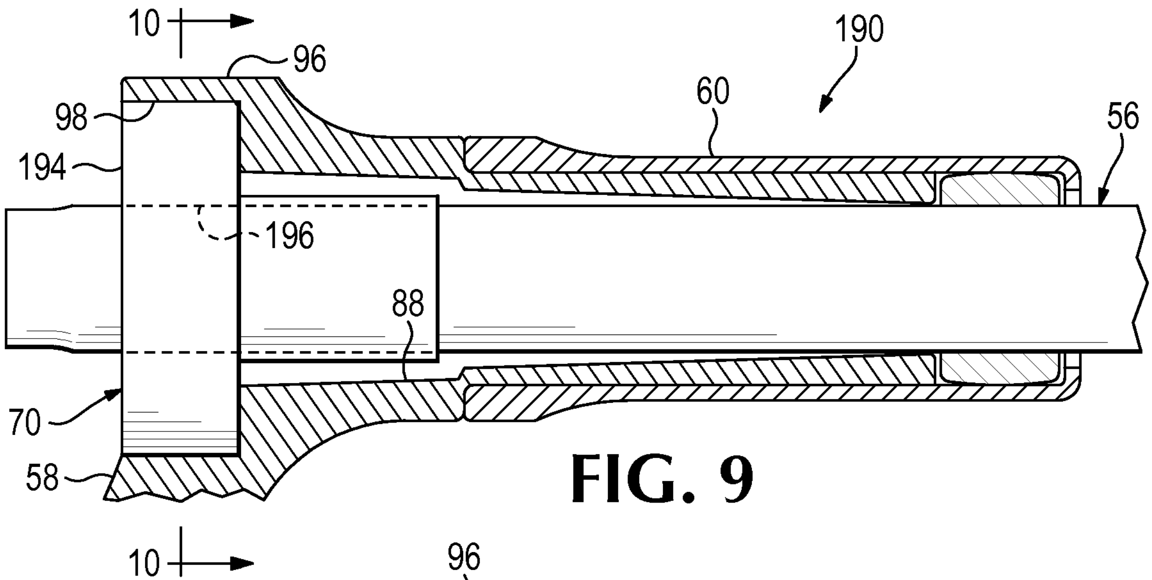


FIG. 9

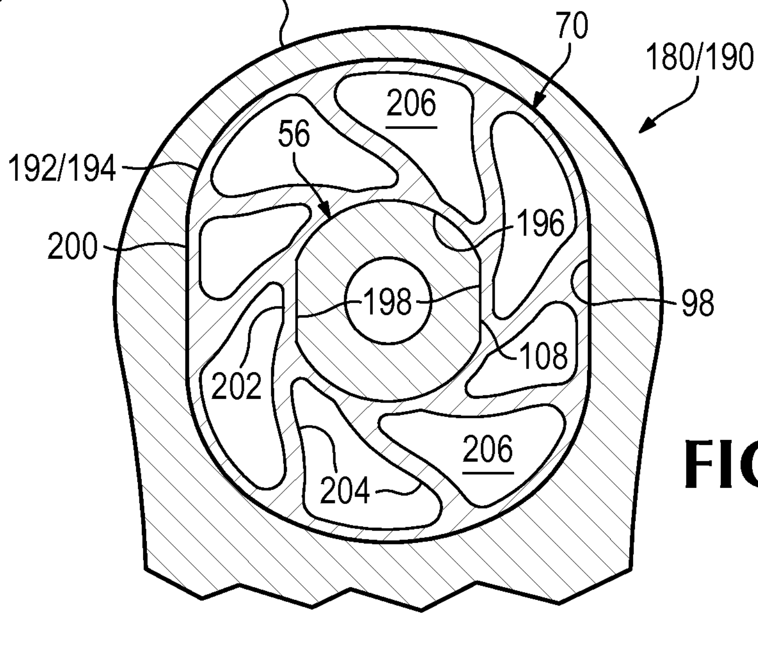


FIG. 10

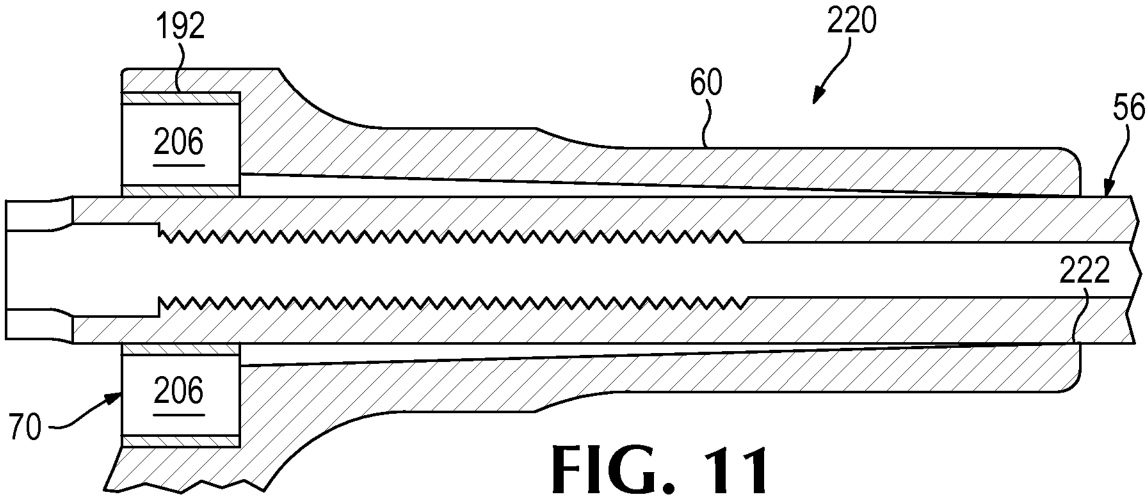


FIG. 11

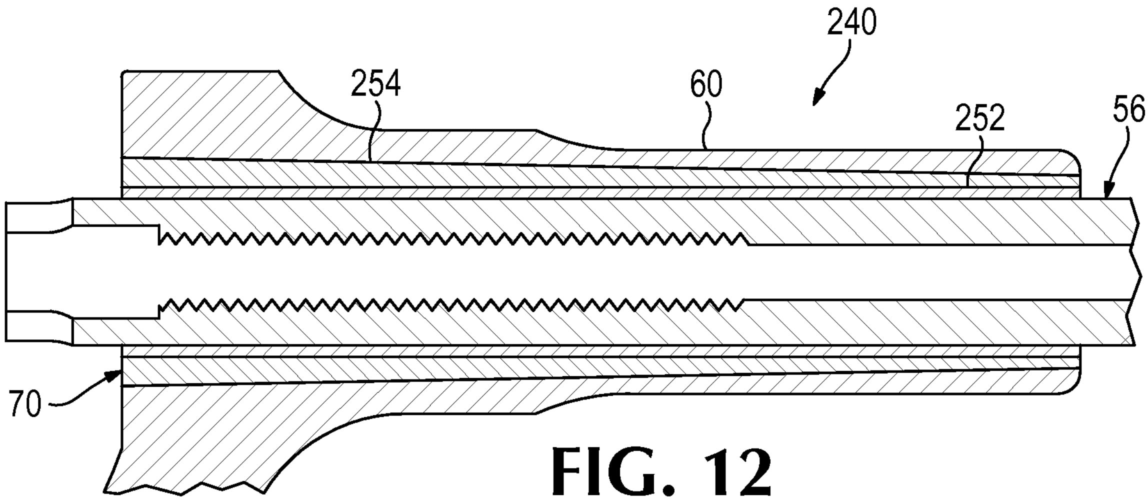


FIG. 12

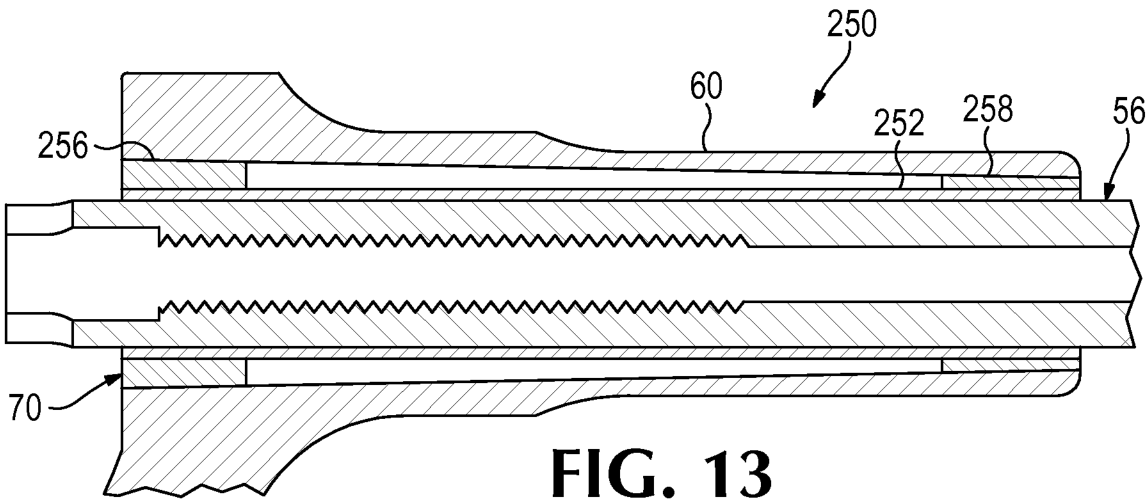
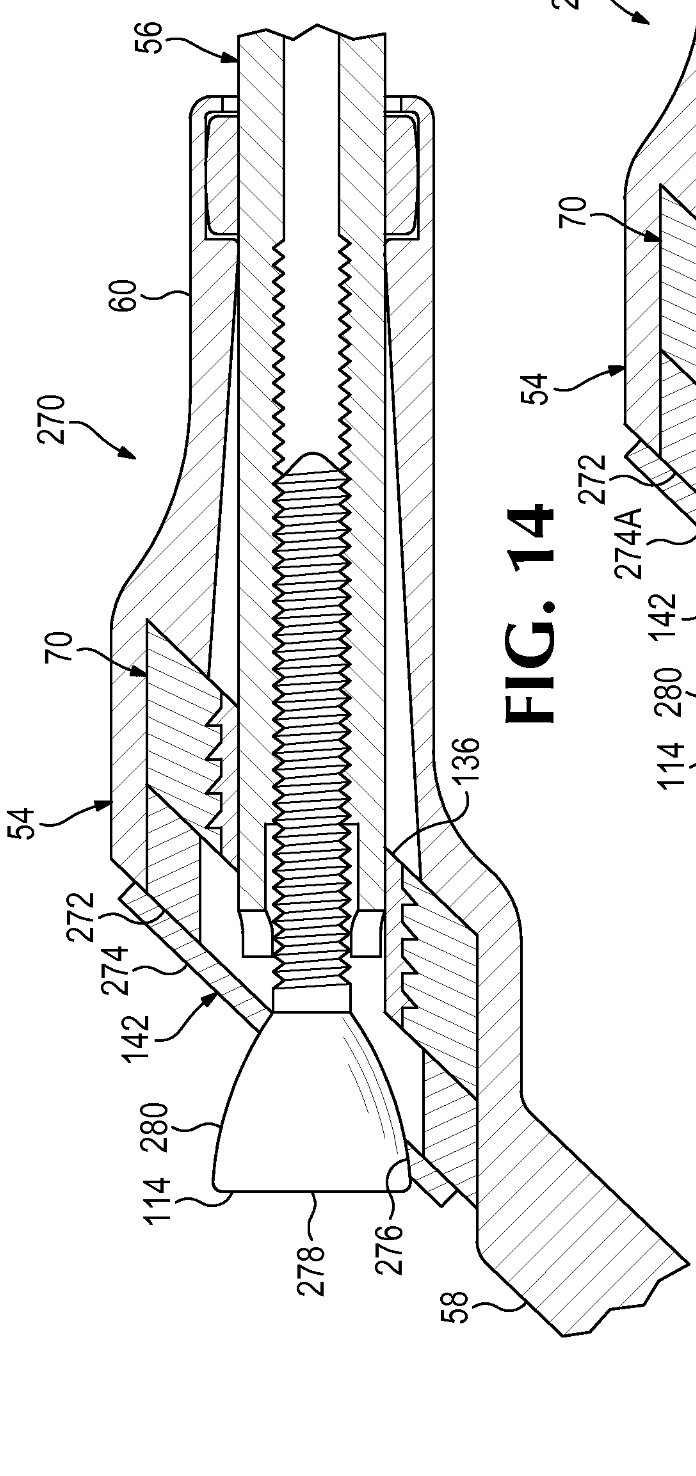


FIG. 13


56
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70
54
272
274
142
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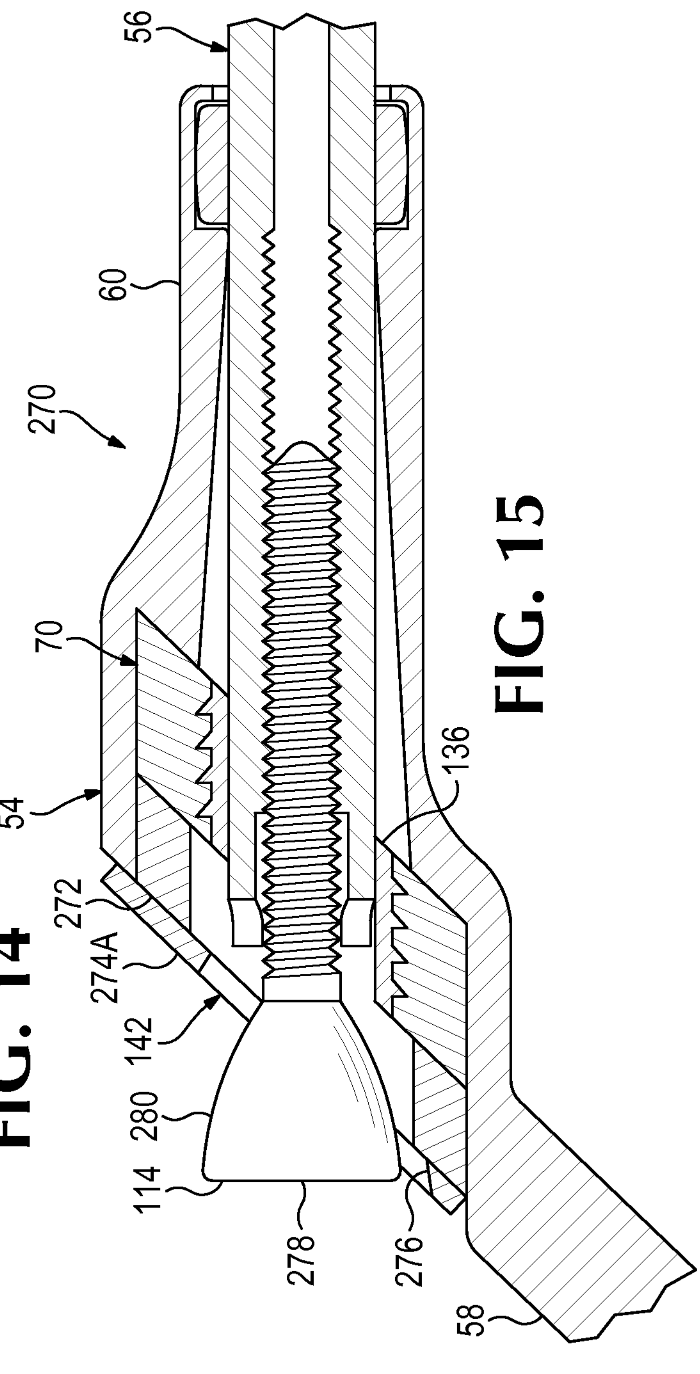
114
278
276
58
136

FIG. 14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136

FIG. 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/069363

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/74 (2015.01)
CPC - A61B 17/748 (2015.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/58, 17/72, 17/74, 17/76, 17/78, (2015.01)
CPC - A61B 17/74, 17/742, 17/744, 17/746, 17/748 (2015.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 606/ 65, 66 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google Scholar, Google.
Search terms used: hip fixation bone plate flexible screw barrel bearing elastomer bushing

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010/0268285 A1 (TIPIRNENI et al) 21 October 2010 (21.10.2010) entire document	1-20
Y	US 6,238,126 B1 (DALL) 29 May 2001 (29.05.2001) entire document	1-20
Y	US 2009/0048606 A1 (TIPIRNENI et al) 19 February 2009 (19.02.2009) entire document	10
Y	US 4,657,001 A (FIXEL) 14 April 1987 (14.04.1987) entire document	11
Y	US 2012/0136356 A1 (DOHERTY et al) 31 May 2012 (31.05.2012) entire document	18-20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 February 2015	26 FEB 2015

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